

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

Medtronic, Inc.,

Plaintiff,

v.

Elan Pharma International Limited,
Elan Pharmaceuticals, Inc., and
Elan Corporation, plc,

Defendants.

**MEMORANDUM OPINION
AND ORDER**

Civil No. 06-1001 ADM/JSM

Jan M. Conlin, Esq., Christopher W. Madel, Esq., and William Manning, Esq., Robins, Kaplan, Miller & Ciresi LLP, Minneapolis, MN, appeared for and on behalf of Plaintiff Medtronic, Inc.

Robert L. Schnell, Esq., Ahna M. Thoresen, Esq., and Nathaniel J. Zylstra, Esq., Faegre & Benson LLP, Minneapolis, MN, appeared for and on behalf of Defendant Elan Pharmaceuticals, Inc.

I. INTRODUCTION

On March 31, 2006, oral argument before the undersigned United States District Judge was heard on Plaintiff Medtronic, Inc.'s ("Medtronic" or "Plaintiff") Motion for a Temporary Restraining Order and Preliminary Injunction [Docket No. 5]. For the reasons set forth herein, the Motion is denied. On April 7, 2006, the parties were notified that the Motion would be denied. This Order sets forth the analysis for the denial.

II. BACKGROUND

Over the last ten years, Medtronic and Defendants Elan Pharma International Limited, Elan Pharmaceuticals, Inc., and Elan Corporation, plc (collectively, "Elan" or "Defendants"), have worked together to expand the pain therapy market for a Medtronic device, the SynchroMed pump. Compl. ¶ 1. A SynchroMed pump is placed under a patient's skin and delivers pain medication intrathecally. Id. A result of the Medtronic/Elan collaboration was a

drug, Prialt, developed by Elan for use with SynchroMed pumps. Id. ¶ 2. The collaboration between Medtronic and Elan was governed by a series of agreements which required Elan, among other responsibilities, to report potential adverse events associated with Prialt to Medtronic, and also to protect Medtronic's confidential information. Compl. Exs. 1-4.

In the spring of 2005, Elan informed Medtronic it was considering selling its Prialt rights to the European market. Elan Ex. List [Docket No. 26] Ex. 5. Throughout 2005, Elan marketed the European rights to Prialt, eventually coming to an agreement with the Japanese company Eisai Co., Ltd. ("Eisai"). Elan Ex. List Ex. 6. Throughout the marketing and sales process, Elan informed Medtronic of its intentions and progress, although the parties dispute how frequently these updates occurred and how specific Elan's updates were.

Medtronic filed suit on March 8, 2006, followed by this Motion for injunctive relief on March 20, 2006. In its Complaint [Docket No. 1], Medtronic alleges Elan breached its agreement with Medtronic, violated the covenant of good faith and fair dealing, has misappropriated Medtronic's trade secrets, and has been unjustly enriched. The instant Motion initially requested relief in the form of an order enjoining Elan from completing its transaction with Eisai. However, the agreement between Elan and Eisai closed on the same date the Motion was filed, thereby mooted Medtronic's original request for relief. Medtronic then amended its Motion to request that the Court bar Elan from conveying any asset, including any intellectual property rights, relating to Prialt or SynchroMed; put the agreement between Elan and Eisai "on hold"; order Elan to attempt to get back any confidential information it has thus far provided to Eisai; and allow Medtronic to review the information Elan has or is expected to transfer to Eisai.

III. DISCUSSION

In determining whether injunctive relief is appropriate, courts must balance the four factors outlined in Dataphase Sys., Inc. v. C.L. Sys., Inc., 640 F.2d 109, 113-14 (8th Cir. 1981) before granting injunctive relief. These factors include: (1) the threat of irreparable harm to the moving party if an injunction is not granted, (2) the harm suffered by the moving party if injunctive relief is denied as compared to the effect on the non-moving party if the relief is granted, (3) the public interest, and (4) the probability that the moving party will succeed on the merits.

A. Irreparable Harm

Medtronic argues that, absent a restraining order, it will be irreparably damaged in two ways.¹ First, Medtronic is concerned that under Elan's agreement with Eisai, Medtronic will not timely receive information regarding potential adverse events related to Prialt and SynchroMed pumps. Second, Medtronic fears that Elan will disclose confidential Medtronic information to Eisai that could benefit Eisai or other Medtronic competitors. Medtronic fails, however, to demonstrate irreparable harm in regard to either concern. It is well established that perceived or potential harm is not sufficient to warrant injunctive relief. "[A]n injunction cannot issue based on imagined consequences of an alleged wrong. Instead, there must be a showing of imminent irreparable injury." In re Travel Comm'n Antitrust Litig., 898 F.Supp. 685, 689 (D. Minn. 1995).

¹ Initially, Medtronic also raised an issue regarding potential lost royalties. However, throughout the briefing and oral argument, it became clear that this issue is not one of irreparable harm, as both parties concede Elan is financially robust and, should occasion arise, able to bear the costs of an adverse judgment. As a result, it is determined that alleged lost royalties would not cause irreparable harm to Medtronic.

With regard to the reporting of adverse events, Medtronic argues that because it has no contractual relationship with Eisai, Eisai is under no obligation to report adverse events involving Prialt and the SynchroMed pump to Medtronic. Medtronic alleges this could potentially prevent Medtronic from properly fulfilling its obligation to report adverse events to certain regulatory agencies, and furthermore, may endanger patients receiving treatment from SynchroMed pumps. However, included in Elan's agreement with Eisai is a clause requiring Eisai to report serious adverse events to Elan within three business days, and non-serious adverse events on a monthly basis. Morris Decl. [Docket No. 29] ¶ 4. In keeping with its current business practice, Elan will forward this information to Medtronic within one business day, thereby allowing Medtronic sufficient time to report adverse events to relevant regulatory agencies. Elan Mem. [Docket No. 25] at 13. Therefore, Medtronic has failed to demonstrate that the reporting of adverse events represents a threat of irreparable harm.

Medtronic also raises the concern that Elan will disclose Medtronic trade secrets to Eisai in violation of Medtronic's agreement with Elan. Medtronic contends that the release of certain trade secrets could potentially constitute misappropriation of trade secrets and cause great harm to Medtronic by allowing competitors access to a bevy of information on confidential Medtronic development processes. For the most part, however, Medtronic has not identified the specific trade secrets over which they have concern. Rather, they identify general categories of information transferred from Elan to Eisai which may potentially contain trade secrets. For example, Medtronic lists the following areas of information which may contain trade secrets: proprietary test protocols; proprietary details regarding the protocols for assuring the stability and compatibility of drugs with the SynchroMed systems; details regarding Medtronic's

confidential protocols; knowledge about developing and testing new drugs for use in the pump; and extensive knowledge about developing and testing drugs and devices for intrathecal drug-infusion therapies. While the concern of Medtronic may be genuine, simply alleging categories of potential trade secrets that may or may not be conveyed to Eisai is not sufficient to demonstrate irreparable harm. Medtronic's concerns simply do not meet the required level of specificity required for injunctive relief. See Internet Inc. v. Tensar Polytechnologies, Inc., Civ. No. 05-317, 2005 WL 2453170, *6 n.8 (D. Minn. Oct. 3, 2005).

The only specific trade secret identified by Medtronic involves certain testing protocols. Although the parties disagree as to whether these protocols disclosed by Elan to Eisai were, in fact, developed by Medtronic, this point is irrelevant, as Medtronic also alleges that Elan has previously publicly published this protocol in a November 2005 presentation by an Elan employee. If this allegation is accepted as true, a restraining order can not now prevent Eisai, or any other competitor of Medtronic, from acquiring that information. If these allegations ultimately are proven at trial, Medtronic may recover damages from Elan for misappropriating trade secrets. However, as the proverbial genie is out of the bottle, a restraining order preventing Elan from transferring the protocols at issue can not accomplish its stated task. Thus, Medtronic fails to demonstrate it will suffer irreparable harm should its Motion be denied.

B. Harm to the Parties

Medtronic alleges if a restraining order is not granted, it will be harmed because of concerns over the reporting of adverse events and potential corruption of Medtronic confidential information. While the Court recognizes, in the abstract, the legitimacy of these concerns, it is not convinced that the harm to Medtronic is imminent or irreparable. Moreover, if Medtronic is

ultimately able to demonstrate a breach of its agreement with Elan, any royalties lost by Medtronic can be remedied by monetary damages.

The potential harm to Elan, should a restraining order be granted, is palpable. Even if the Court were to grant Medtronic's revised request to put the Elan/Eisai agreement "on hold," this would result in major complications for Elan. Medtronic's request, in effect, would require Elan to immediately cease providing information to Eisai, and attempt to retrieve the information it has already given to Eisai. In essence, the injunctive relief would reverse the Elan/Eisai transaction, potentially exposing Elan to an action by Eisai for failure to perform its obligations under its agreement. Additionally, Medtronic requests an escrow of fifty million dollars, which represents the payment from Eisai to Elan, thereby preventing Elan from returning payment to Eisai. Halting or reversing a \$100 million transaction is extraordinary relief. Medtronic has not met its burden in demonstrating that any harm it may suffer warrants such drastic action.

In sum, the harm that Elan would incur should the restraining order be granted is significant, while the harm to Medtronic should the restraining order be denied may or may not materialize. As a result, this factor weighs heavily in favor of Elan.

C. Public Benefit

Although the parties both argue the public benefit weighs in their favor, the concerns cited by the parties are, at best, general and tenuously connected to the facts presented. Medtronic argues that the public has an interest in ensuring that contracts and agreements are properly enforced. Additionally, Medtronic raises the concern that if it does not timely receive reports of adverse events, the safety of patients using SynchroMed pumps could be endangered. In response, Elan argues that granting the restraining order would significantly delay a powerful

pain medication from the European market. While all of these concerns can be considered theoretical public interests on a broad scale, neither side has identified a clearly discernable public benefit. As such, this factor favors neither party.

D. Likelihood of Success on the Merits

Given Medtronic's failure to demonstrate the existence of irreparable harm and the potential harm to Elan, whether Medtronic can or is likely to succeed on the merits of the case does not change the result here. Medtronic's allegations, if ultimately proven at trial, could certainly prove valid and result in a very significant judgment. However, because Medtronic has not demonstrated that the other Dataphase factors weigh in their favor, whether they are likely to succeed at trial can not tip the scales sufficiently to support granting Medtronic's Motion. Based on the showing to date, the heavy burden required to be demonstrated by Plaintiff has not been met. "If the chance of irreparable injury to the movant should relief be denied is outweighed by the likely injury to other parties litigant should the injunction be granted, the moving party faces a heavy burden of demonstrating that he is likely to prevail on the merits." Dataphase, 640 F.2d at 113.

IV. CONCLUSION

For the reasons stated on the record, and based on all the files, records and proceedings herein, **IT IS HEREBY ORDERED** that Plaintiff's Motion for Temporary Restraining Order [Docket No. 5] is **DENIED**.

BY THE COURT:

s/Ann D. Montgomery
ANN D. MONTGOMERY
U.S. DISTRICT JUDGE

Dated: April 13, 2006.